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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,741	12/21/2001	Jiri Aubrecht	PC11099AGLK	5052

7590

01/06/2003

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EXAMINER

WESSENDORF, TERESA D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,741

Applicant(s)

AUBRECHT ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to an assay method.
- II. Claims 8-15, drawn to a cell.
- III. Claim 16, drawn to a bioluminescent reverse mutagenicity assay method.
- IV. Claims 17-21, drawn to an assay method that produces an amount of ATP.
- V. Claim 23, drawn to a method of determining the structure and chemical characteristics of a compound comprising contacting bacterial cells with a compound library.
- VI. Claim 24, drawn to a method of determining the structure and chemical characteristics of compound comprising contacting a mammalian cell with a compound from a library.

The inventions are distinct, each from the other because of the following reasons:

Art Unit: 1639

Inventions I and III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods comprising of different, distinct process steps utilizing different components and/or conditions producing different results.

Inventions II and I, III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different statutory subject matters, such as cells and methods. The claimed cells can be used in the different and distinct methods, as recited.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for Group I is not required for Group II-VI, restriction for examination purposes as indicated is proper.

During a telephone conversation with Gabriel Kleiman on 12/17/02 a provisional election was made with traverse to

Art Unit: 1639

prosecute the invention of Group II, claims 8-15. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 1-7 and 16-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Status of Claims

Claims 8-15 are under consideration.

Claims 1-7 and 16-24 are withdrawn from consideration as being drawn to non-elected invention.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical, idiomatic and grammatical). Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Art Unit: 1639

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 8 is indefinite since the language "substantially reversible point mutation" is not a positive characterization of a cell composition (and relates more to a process). It is suggested that applicants recite a component e.g., the mutated form of the gene. The term "substantially" in claim 8 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Also, the term "expressible" connotes indefiniteness that the cell may not express said gene and relates more to the ability of a cell

Art Unit: 1639

rather than a positive recitation of a component of a cell. [It is suggested that applicants change the term to -expressed-].

B. Claims 10, 12 and 15 are indefinite in the designation of the different bacterial strains. It is suggested that applicants positively recite the different designations e.g. *S. typhimurium* TA 100 lux is a mutant of e.g., his or trp or ser.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Larossa et al (WO 94/13831).

Larossa discloses a cell which contains and expresses a heterologous DNA construct (page 9, lines 1-6) as the lux(CDABE)gene (page 19, lines 31-33; page 12, lines 14-17; page 2, line 23 up to page 3, line 7; page 4, lines 1-10; page 5, lines 8-11) and the transformation of said cell by mutating the histidine codon (page 58, Example 17; page 13, line 17; page 21, lines 9-25 and page 50, Table V) and serine hydroxamate

Art Unit: 1639

(page 59, lines 12 up to page 60, line 15). The cell E. coli and Salmonella typhimurium is disclosed at page 17, lines 10-14.

Accordingly, Larossa disclosure of the E. Coli and S, Typhimurium expressing lux gene complex and His or Ser mutation fully meets the broadly claimed cell.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being obvious LaRossa et al in view of Green et al (Mutation Research).

LaRossa is described above. LaRossa does not disclose a tryptophan (trp) mutation as claimed. Green discloses at page 4, col. 1 and col. 2, an E. coli strain Trp mutation and the simplicity, speed and sensitivity of mutagen screening with the E. coli Trp derivatives. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to mutate the Trp of E.coli or S. typhimurium

Art Unit: 1639

of LaRossa since Green discloses said Trp mutant derivatives and the advantages in derived in such mutation and the motivation for a skilled artisan to use Trp mutant, as described by Green, above.

No claim is allowed.

REASSIGNMENT OF LOCATION

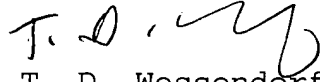
The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Art Unit: 1639

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

December 27, 2002